

§ 520.154

21 CFR Ch. I (4–1–14 Edition)

§ 520.154 Bacitracin oral dosage forms.

§ 520.154a Bacitracin methylene disalicylate.

(a) *Specifications.* Each pound of soluble powder contains the equivalent of 50 grams of bacitracin activity for use as in paragraph (d)(1) or (d)(2) of this section, or the equivalent of 200 grams of bacitracin activity for use as in paragraph (d) of this section.

(b) *Sponsor.* See No. 046573 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.70 of this chapter.

(d) *Conditions of use*—(1) *Growing turkeys*—(i) *Amount.* 400 milligrams (mg) per gallon (gal) in drinking water.

(ii) *Indications for use.* Aid in the control of transmissible enteritis complicated by organisms susceptible to bacitracin methylene disalicylate.

(iii) *Limitations.* Prepare a fresh solution daily.

(2) *Broiler and replacement chickens*—(i) *Amount.* 100 mg per gal in drinking water.

(A) *Indications for use.* Aid in the prevention of necrotic enteritis caused by *Clostridium perfringens* susceptible to bacitracin methylene disalicylate.

(B) *Limitations.* Prepare a fresh solution daily.

(ii) *Amount.* 200 to 400 mg per gal in drinking water. Administer continuously 5 to 7 days or as long as clinical signs persist, then reduce to prevention levels (100 mg/gal).

(A) *Indications for use.* Treatment of necrotic enteritis caused by *C. perfringens* susceptible to bacitracin methylene disalicylate.

(B) *Limitations.* Prepare a fresh solution daily.

(3) *Swine*—(i) *Amount.* 1 gram per gallon in drinking water.

(ii) *Indications for use.* Treatment of swine dysentery associated with *Treponema hyodysenteriae*. Administer continuously for 7 days or until signs of dysentery disappear.

(iii) *Limitations.* Prepare a fresh solution daily. Treatment not to exceed 14 days. If symptoms persist after 4 to 5 days consult a veterinarian. Not to be given to swine that weigh more than 250 pounds.

(4) *Growing quail*—(i) *Amount.* 400 mg per gal in drinking water.

(ii) *Indications for use.* For prevention of ulcerative enteritis due to *Clostridium colinum* susceptible to bacitracin methylene disalicylate.

(iii) *Limitations.* Prepare fresh solution daily. Use as sole source of drinking water.

[57 FR 37322, Aug. 18, 1992; 57 FR 42623, Sept. 15, 1992, as amended at 63 FR 38474, July 17, 1998; 64 FR 13068, Mar. 17, 1999; 76 FR 53050, Aug. 25, 2011]

§ 520.154b Bacitracin methylene disalicylate and streptomycin sulfate powder.

(a) *Specifications.* Each gram of powder contains 200 units bacitracin methylene disalicylate and streptomycin sulfate equivalent to 20 milligrams of streptomycin.

(b) *Sponsor.* See No. 046573 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount.* Administer 1 level teaspoonful per 10 pounds of body weight three times daily, mixed in a small quantity of liquid or feed.

(2) *Indications for use.* For the treatment of bacterial enteritis caused by pathogens susceptible to bacitracin and streptomycin such as *Escherichia coli*, *Proteus* spp., *Staphylococcus* spp., and *Streptococcus* spp., and for the symptomatic treatment of associated diarrhea.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[71 FR 17702, Apr. 7, 2006]

§ 520.154c Bacitracin zinc soluble powder.

(a) *Specifications.* Each pound contains the equivalent of not less than 5 grams of bacitracin.

(b) *Sponsor.* See No. 053501 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.70 of this chapter.

(d) *Conditions of use*—(1) *Broiler chickens*—(i) *Amount.* 100 milligrams per gallon in drinking water.

(A) *Indications for use.* Prevention of necrotic enteritis caused by *Clostridium perfringens* susceptible to bacitracin zinc.

(B) *Limitations.* Prepare a fresh solution daily.

(ii) *Amount.* 200 to 400 milligrams per gallon in drinking water.

(A) *Indications for use.* Control of necrotic enteritis caused by *Clostridium perfringens* susceptible to bacitracin zinc.

(B) *Limitations.* Prepare a fresh solution daily.

(2) *Growing quail*—(i) *Amount.* 500 milligrams per gallon in drinking water for 5 days followed by 165 milligrams per gallon in drinking water for 10 days.

(ii) *Indications for use.* Control of ulcerative enteritis caused by *Clostridium* spp. susceptible to bacitracin zinc.

(iii) *Limitations.* Prepare a fresh solution daily.

[57 FR 37322, Aug. 18, 1992, as amended at 67 FR 78355, Dec. 24, 2002]

§ 520.222 Bunamidine hydrochloride.

(a) *Chemical name.* *N,N*-Dibutyl-4-(hexyloxy)-1-naphthamidine hydrochloride.

(b) *Specifications.* The drug is an oral tablet containing 100, 200, or 400 milligrams of bunamidine hydrochloride.

(c) *Sponsor.* See No. 000061 in § 510.600(c) of this chapter.

(d) *Conditions of use.* (1) The drug is intended for oral administration to dogs for the treatment of the tapeworms *Dipylidium caninum*, *Taenia pisiformis*, and *Echinococcus granulosus*, and to cats for the treatment of the tapeworms *Dipylidium caninum* and *Taenia taeniaeformis*.

(2) It is administered to cats and dogs at the rate of 25 to 50 milligrams per kilogram of body weight. The drug should be given on an empty stomach and food should not be given for 3 hours following treatment.

(3) Tablets should not be crushed, mixed with food, or dissolved in liquid. Repeat treatments should not be given within 14 days. The drug should not be given to male dogs within 28 days prior to their use for breeding. Do not administer to dogs or cats having known heart conditions.

(4) For use only by or on the order of a licensed veterinarian.

[40 FR 13838, Mar. 27, 1975, as amended at 42 FR 13018, Mar. 8, 1977; 46 FR 48642, Oct. 2, 1981; 61 FR 8873, Mar. 6, 1996; 62 FR 61624, Nov. 19, 1997]

§ 520.246 Butorphanol tartrate tablets.

(a) *Specifications.* Each tablet contains 1, 5, or 10 milligrams of butorphanol base activity as butorphanol tartrate.

(b) *Sponsor.* See No. 000856 in § 510.600(c) of this chapter.

(c) *Conditions of use.* The drug is used for the treatment of dogs as follows:

(1) *Amount.* 0.25 milligram of butorphanol base activity per pound of body weight.

(2) *Indications for use.* For the relief of chronic nonproductive cough associated with tracheo-bronchitis, tracheitis, tonsillitis, laryngitis, and pharyngitis associated with inflammatory conditions of the upper respiratory tract.

(3) *Limitations.* For oral use in dogs only. Repeat at intervals of 6 to 12 hours as required. If necessary, increase dose to a maximum of 0.5 milligram per pound of body weight. Treatment should not normally be required for longer than 7 days. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[47 FR 14702, Apr. 6, 1982, as amended at 53 FR 27851, July 25, 1988]

§ 520.260 *n*-Butyl chloride.

(a)(1) *Specifications.* *n*-Butyl chloride capsules, veterinary contain 272 milligrams or 816 milligrams of *n*-butyl chloride in each capsule.

(2) *Sponsor.* See No. 021091 in § 510.600(c) of this chapter.

(3) *Conditions of use.* (i) It is used for the removal of ascarids (*Toxocara canis* and *Toxascaris leonina*) and hookworms (*Ancylostoma caninum*, *Ancylostoma braziliense*, and *Uncinaria stenocephala*) from dogs and of the ascarid (*Toxocara cati*) and hookworm (*Ancylostoma tubaeforme*) from cats.

(ii)(a) Animals should not be fed for 18 to 24 hours before being given the drug. Puppies and kittens should be wormed at 6 weeks of age. However, if heavily infested, they may be wormed at 4 or 5 weeks of age. Administration of the drug should be followed in ½ to 1 hour with a teaspoonful to a tablespoonful of milk of magnesia or 1 or 2 milk of magnesia tablets. Normal rations may be resumed 4 to 8 hours after treatment. Puppies and kittens should